

U.S. Patent Application Serial No. 09/509,449
Amendment dated December 7, 2006
Reply to Final Office Action of June 6, 2006

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REMARKS

Applicant respectfully requests entry of the amendment and reconsideration of the claims in view of the following remarks. Claims 21, 23, and 28 have been amended to further clarify the claimed invention. Claims 30-41 are newly presented. Applicant submits the amendment places the claims in condition for allowance. After entry of the amendment, claims 18 and 20-41 will be pending.

Applicant submits the amendment is supported by the specification and does not raise any issues of new matter.

35 U.S.C. § 103

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Lacroix, and Seidel

Claims 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either Lacroix or Seidel et al. Applicant respectfully traverses this rejection.

The Office Action alleges the method disclosed by Ling is only limited in that the two different immunoreactants used to detect the antigen and antibody in the sample must be non-complimentary to each other. From this teaching, the Office Action alleges it would have been apparent to one of skill in the art that the antigen and antibody combination recited in the claims is a functional equivalent of the non-complimentary antigen and antibody combination disclosed by Ling and the different antigen and antibody combination disclosed by Schönbrunner. Applicant respectfully does not agree.

In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art. The equivalency cannot be based on Applicant's disclosure or the mere fact that the components at issue are functional equivalents. *In re Ruff*, 256 F.2d 590 (CCPA 1958); MPEP § 2144.06. Neither Ling nor Schönbrunner, alone or in combination, recognize that the claimed combination of antigen and antibody is functionally equivalent to the combination of antigen and antibody disclosed in Ling or Schönbrunner. The mere fact that the claimed combination of antigen and antibody may be

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functionally equivalent to the non-complimentary antigen and antibody disclosed by Ling or Schönbrunner is not sufficient to meet the Examiner's burden under MPEP § 2144.06.

Moreover, Schönbrunner teaches away from using a single class of antigen to detect virus in a simultaneous detection assay. In order to prevent false positives and/or false negatives, Schönbrunner discloses a simultaneous detection assay that detects (1) a first class of antigen in the specimen and (2) antibody to a second class of antigen in the specimen that is different than the first antigen (Schönbrunner at page 5, line 33 to page 6, line 13). For example, Schönbrunner discloses that if the first analyte is a gag antigen, the second analyte is an anti-capsid antibody or anti-envelope antibody. Schönbrunner therefore teaches away from a detection assay that includes, for example, a first analyte that is a p7 antigen and a second analyte that is an anti-p7 antibody.

In view of the teachings of Schönbrunner, one of skill in the art would not have been motivated to modify Ling to meet the requirements of Applicant's claims. The working examples in Ling only disclose using different proteins (e.g. anti-HBs antibodies in combination with HBc core antigen) for detection of the antigen and antibody. Therefore, neither Ling nor Schönbrunner, alone or in combination, teaches or suggests using different epitopes on the same protein for detection of the antigen and antibody.

The Office Action alleges the arguments provided in the previous Office Action were based solely on the teachings of Schönbrunner and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. Applicants respectfully do not agree.

It is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983); MPEP § 2145(X)(B)(2). As discussed above, Schönbrunner teaches away from using a single class of antigen to detect virus in a simultaneous detection assay. In view of these teachings, one of skill in the art would not have been motivated to combine Ling and Schönbrunner to meet the requirements of Applicant's claims. Absent Applicant's teachings, there is no motivation to combine Ling and Schönbrunner.

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Absent the combination of Ling and Schönbrunner, there is no motivation to combine the disclosure of Masalova and Papatheodoridis, or of Simmonds, with Seidel or Lacroix. Lacroix and Seidel do not describe or suggest selecting an antigen as the first analyte and an antibody as the second analyte so that the second analyte antibody is an antibody to the first analyte antigen.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also contains a motivation or suggestion to modify or combine the references. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). Absent Applicant's disclosure, one of skill in the art would not have been motivated to combine the references as recited in the Office Action. Therefore, the Office Action has failed to establish a *prima facie* case of obviousness. Withdrawal of the rejection is respectfully requested.

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng, and Khanna

Claims 21, 23, and 25-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further view of either of Cheng or Khanna. Applicant respectfully traverses this rejection.

Applicant submits the Office Action has failed to establish a *prima facie* case of obviousness based on the combination of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner for the reasons discussed above.

Cheng and Khanna do not cure the deficiencies of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner. Cheng and Khanna show the use of detergents in the case of use as analyte-biotin bidentate reagent or in the case of decreasing complex formation. However, these uses are completely different from the use in the present invention. In addition, Cheng describes on column 7, lines 26 to 35, "the detergent(s) that may be employed in accordance with the methods of the present invention include anionic detergents, cationic detergents(s), Zwitterionic detergents, and nonionic detergents." Therefore, Cheng provides no expectation of success because it merely provides a blanket disclosure of all kinds of detergents without identifying any in particular for use as claimed and without providing any expectation that any particular detergents would work with the invention as claimed.

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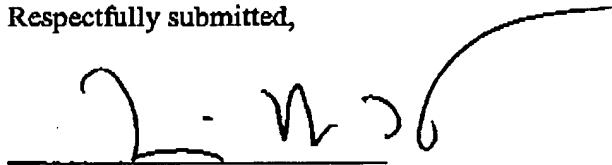
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In view of the forgoing, Applicants assert that the combination of Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng and Khanna fails render to the claims as amended obvious. Withdrawal of the rejection is respectfully requested.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,



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